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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/769,565 | 01/29/2004 | Mary Mah Lee Ng | 59419-010102 | 9294 |

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| EXAMINER | |
|---|---|
| SALVOZA, M FRANCO G | |
| ART UNIT | PAPER NUMBER |
| 1648 | |

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/769,565 | NG ET AL. | |
| | Examiner | Art Unit | |
| | M. Franco Salvoza | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

The claims are numbered improperly, as there are two claim 21's. Examiner presumes the second claim 21 is supposed to be claim 22. For the purposes of compact prosecution, the examiner has treated the claims accordingly. However, this treatment does not relieve applicant of the burden of correcting.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 14-16 drawn to a kit and a method for controlling a flavivirus entry into a cell for comprising administering an agent interfering with a flavivirus receptor protein substantially homologous to SEQ ID 1, classified in class 424, subclass 130.1.

II. Claims 1-11, 14-16 drawn to a kit and a method for controlling a flavivirus entry into a cell for comprising administering an agent interfering with a flavivirus receptor protein substantially homologous to SEQ ID 2, classified in class 424, subclass 130.1.

III. Claims 1-11, 14-16 drawn to a kit and a method for controlling a flavivirus entry into a cell for comprising administering an agent interfering with a flavivirus receptor protein substantially homologous to SEQ ID 3, classified in class 424, subclass 130.1.

IV. Claims 1-11, 14-16 drawn to a kit and a method for controlling a flavivirus entry into a cell for comprising administering an agent interfering with a flavivirus

receptor protein substantially homologous to SEQ ID 4, classified in class 424, subclass 130.1.

V. Claims 1-11, 14-16 drawn to a kit and a method for controlling a flavivirus entry into a cell for comprising administering an agent interfering with a flavivirus receptor protein substantially homologous to SEQ ID 5, classified in class 424, subclass 130.1.

VI. Claims 12-13, 17-18 drawn to a kit and a method for controlling flavivirus entry into a cell, comprising administering to the cell an agent interfering with the expression of a flavivirus receptor protein, classified in class 536, subclass 23.1.

VII. Claims 19-23, drawn to a kit and a method for controlling a flavivirus entry into a cell, the cell having a plasma membrane, classified in class 424, subclass 130.1.

VIII. Claims 24-28, drawn to a kit and a method for controlling a flavivirus entry into a cell, classified in class 424, subclass 130.1.

IX. Claims 29-44, drawn to a method for controlling entry of a flavivirus into a cell using a sequence substantially homologous to SEQ ID 19, a pharmaceutical composition, a method for inducing immunity, and a vaccine classified in class 930, subclass 10.

X. Claims 29-44, drawn to a method for controlling entry of a flavivirus into a cell using a sequence substantially homologous to SEQ ID 21, a pharmaceutical composition, a method for inducing immunity, and a vaccine classified in class 930, subclass 10.

XI. Claims 45, 46, drawn to a kit and a method for diagnosing a flavivirus infection in

a vertebrate susceptible to infection, classified in class 930, subclass 10.

XII. Claims 47, 48 drawn to a kit and a diagnostic method to analyze a cell susceptibility to flavivirus infection, classified in class 930, subclass 10.

XIII. Claim 49, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 1, classified in class 930, subclass 10.

XIV. Claim 49, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 2, classified in class 930, subclass 10.

XV. Claim 49, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 3, classified in class 930, subclass 10.

XVI. Claim 49, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 4, classified in class 930, subclass 10.

XVII. Claim 49, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 5, classified in class 930, subclass 10.

XVIII. Claim 50, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 20, classified in class 930, subclass 10.

XIX. Claim 50, drawn to an isolated purified polypeptide from Vero cells substantially homologous to SEQ ID 21, classified in class 930, subclass 10.

XX. Claim 51, drawn to an antibody comprising portions substantially homologous to SEQ ID 1, classified in class 424, subclass 130.1.

XXI. Claim 51, drawn to an antibody comprising portions substantially homologous to SEQ ID 2, classified in class 424, subclass 130.1.

XXII. Claim 51, drawn to an antibody comprising portions substantially homologous to

SEQ ID 3, classified in class 424, subclass 130.1.

XXIII. Claim 51, drawn to an antibody comprising portions substantially homologous to SEQ ID 4, classified in class 424, subclass 130.1.

XXIV. Claim 51, drawn to an antibody comprising portions substantially homologous to SEQ ID 5, classified in class 424, subclass 130.1.

XXV. Claim 52, drawn to an antibody comprising portions substantially homologous to SEQ ID 19, classified class 424, subclass 130.1.

XXVI. Claim 52, drawn to an antibody comprising portions substantially homologous to SEQ ID 21, classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I-V, IX, X, XIII-XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121. Absent evidence to the contrary, each such sequence represents an independent and distinct invention due to structural divergence in sequence and functional divergence for encoding different products, subject to a restriction requirement pursuant to 35 U.S.C. § 121 and 37 CFR 1.141 et seq. (MPEP § 803.04).

Inventions I-V, VI, VII, VIII, IX-X, XI, XII, XIII-XVII, XVIII-XIX, and XX-XXVI are separate products having distinct functions, distinct structures, and distinct physical, chemical and functional properties requiring separate searches of the prior art. The kits utilize distinct

products to carry out the separate method steps, one using antibody as interfering agent, another using nucleic acid molecules and another method using a vaccine and envelope protein for a separate method.

Inventions XIII-XIX are distinct products because the isolated and purified peptides comprise distinct amino acid sequences that fold into different proteins to create different structural characteristics and functions.

Inventions XX-XXVI are distinct products because the antibodies comprise distinct amino acid sequences that fold into different proteins to create different structural characteristics and binding properties.

Inventions XIII-XIX and XX-XXVI are distinct products because the polypeptides and antibodies have distinct structures and functions. Antibodies share a common structure of light and heavy chains, while the polypeptides possess a wide variety of different structures, which affect function.

Inventions I-V, VI, VII, VIII, IX-X, XI, and XII are separate methods with patentably distinct steps and effects requiring separate searches of the prior art. Each method requires different steps and different products to carry out the method steps. For example, the method for diagnosing an infection is distinct, uses different products and requires different steps from a method for treating infection or controlling flavivirus entry into a cell.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for the other Groups, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116. Amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be

amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. Franco Salvoza
Patent Examiner

SHANON FOLEY
PRIMARY EXAMINER